IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA USA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-552-GBW-SRF
	)	
IPSEN BIOPHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently before the court in this civil action for violations of the Lanham Act, 15 U.S.C. § 1125(a), and related state law causes of action is the motion of defendant Ipsen Biopharmaceuticals, Inc. ("Ipsen") to dismiss the complaint for lack of subject matter jurisdiction and failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively. (D.I. 16)[1] For the following reasons, I recommend that the court DENY Ipsen's motion to dismiss.

I. BACKGROUND

Ipsen is a biopharmaceutical drug company. (D.I. 1 at ¶ 1) In August of 2007, Ipsen began manufacturing Somatuline® Depot, a drug injection with the active ingredient lanreotide acetate, to treat rare diseases by slowing the growth of tumors. (*Id.* at ¶¶ 1, 34) The Centers for Medicare and Medicaid Services ("CMS") assigned Somatuline® Depot a billing code of J1930 under the Healthcare Common Procedure Coding System ("HCPCS"). (*Id.* at ¶¶ 5(b); 36)

On August 31, 2020, Ipsen filed a lawsuit against the U.S. Department of Health and Human Services ("HHS") challenging a decision of the U.S. Food and Drug Administration

[1] The briefing and related filings associated with the pending motion to dismiss are found at D.I. 17, D.I. 21, D.I. 23, and D.I. 33.

("FDA") to continue regulating Somatuline® Depot as a drug product instead of regulating it as a biological product. (D.I. 1 at ¶ 53) The U.S. District Court for the District of Columbia dismissed Ipsen's suit in September of 2021 for lack of subject matter jurisdiction because no follow-on products had been approved by the FDA that would cause harm to Ipsen. (*Id.* (citing *Ipsen Biopharms., Inc. v. Becerra*, 2021 WL 4399531 (D.D.C. Sept. 24, 2021)).

On December 17, 2021, the U.S. Food and Drug Administration ("FDA") approved a lanreotide acetate product manufactured by InvaGen Pharmaceuticals, Inc. ("InvaGen"), an affiliate of plaintiff Cipla USA, Inc. ("Cipla"). (D.I. 1 at ¶¶ 2, 39) The FDA's approval was made under the Section 505(b)(2) pathway for New Drug Approvals ("NDAs"), which establishes that a product is safe and effective for its intended use without rendering any findings of therapeutic equivalence. (*Id.* at ¶ 3) Cipla represented in a subsequent press release that the active ingredient, route of administration, and strengths of InvaGen's lanreotide acetate product ("InvaGen's Product") are the same as Somatuline® Depot. (*Id.* at ¶ 40) Cipla also submitted a petition requesting that the FDA designate InvaGen's Product as therapeutically equivalent to Somatuline® Depot. (*Id.* at ¶ 3) The petition remains pending. (*Id.*)

Cipla launched InvaGen's Product on February 10, 2022. (D.I. 1 at ¶ 43) On February 24, 2022, Ipsen filed an application with CMS to ensure that reimbursement claims for InvaGen's Product would be rejected unless they were submitted using the miscellaneous HCPCS code, J3490. (*Id.* at ¶ 46) At the same time, the complaint alleges that Ipsen began disseminating false or misleading statements about InvaGen's Product to providers and wholesale distributors. (*Id.* at ¶ 47) These false or misleading statements centered on two subjects: (1) the proper HCPCS code for InvaGen's Product and the resulting reimbursement problems from a failure to use the proper HCPCS code; and (2) Ipsen's accusation that Cipla

falsely claimed InvaGen's Product was "therapeutically equivalent" to Somatuline® Depot. (*Id.* at ¶¶ 47-48) Cipla experienced a drop in demand for InvaGen's Product after Ipsen made its false or misleading statements. (*Id.* at ¶ 50)

On March 30, 2022, Ipsen filed a new complaint against HHS challenging the FDA's decision not to regulate Somatuline® Depot as a biological product. (D.I. 1 at ¶ 54) Ipsen's complaint alleges that Cipla sells InvaGen's Product at substantially lower prices than Somatuline® Depot and asks the FDA to withdraw its approval for InvaGen's Product. (*Id.*) The following month, Cipla filed this civil action against Ipsen, alleging causes of action for unfair competition under the Lanham Act, 15 U.S.C. § 1125(a), and Delaware common law; deceptive trade practices under the Delaware Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2532; tortious interference with economic advantage; and trade libel. (*Id.* at ¶¶ 57-99) Ipsen filed a motion to dismiss Cipla's complaint on June 3, 2022. (D.I. 16)

On July 6, 2022, CMS issued decisions creating a new HCPCS code for InvaGen's Product[2] and affirming that Ipsen's Somatuline® Depot continues to belong in its existing HCPCS code.[3] (D.I. 32, Ex. A at 10) CMS declined to revise the code description for Somatuline® Depot to include the brand name, finding that a new descriptor for Somatuline® Depot was unnecessary due to the possibility that generic formulations of lanreotide acetate may fall within the code for Somatuline® Depot in the near future. (*Id.* at 11-12) CMS's HCPCS coding decision for InvaGen's Product became effective as of October 1, 2022. (*Id.* at 10)

[2] The new HCPCS Level II code for InvaGen's Product is J1932. (D.I. 32, Ex. A at 10)
[3] Ipsen's Somatuline® Depot product is covered by existing code J1930. (D.I. 32, Ex. A at 10)

II. LEGAL STANDARDS

A. Failure to State a Claim

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 790-91 (3d Cir. 2016).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

The court's determination is not whether the non-moving party "will ultimately prevail," but whether that party is "entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations and quotation marks omitted). This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element]." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task

requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

B. Subject Matter Jurisdiction

Rule 12(b)(1) allows for dismissal of a complaint for lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). There is no dispute in this case that Ipsen's motion to dismiss under Rule 12(b)(1) presents a facial challenge to the court's subject matter jurisdiction under the doctrine of preemption. (D.I. 17 at 8; D.I. 21 at 6); *see Nowak v. Major League Soccer, LLC*, 90 F. Supp. 3d 382, 386-88 (E.D. Pa. 2015) (analyzing preemption argument as a facial challenge to the court's subject matter jurisdiction). A facial challenge under Rule 12(b)(1) "is reviewed under the same standard as a Rule 12(b)(6) motion." *Harrison v. Soroof Int'l, Inc.*, 320 F. Supp. 3d 602, 610 (D. Del. 2018).

III. DISCUSSION

A. The Medicare Statute Does Not Preclude Judicial Review of Cipla's Claims.

Ipsen argues that all counts of Cipla's complaint must be dismissed because they require this court to decide whether InvaGen's Product belongs in the same HCPCS code as Somatuline® Depot. (D.I. 17 at 8) According to Ipsen, this inquiry is expressly barred by the Medicare statute, 42 U.S.C. § 1395w-3a(j)(1), which precludes judicial review of claims relating to the assignment of HCPCS codes. (*Id.* at 9) Cipla responds that this provision is inapplicable to the assignment of HCPCS codes by CMS, an assertion which Ipsen challenges in its reply brief. (D.I. 21 at 6-7; D.I. 23 at 2) The court need not resolve the parties' dispute regarding the proper interpretation of the Medicare statute, however, because the pleaded allegations do not require this court to make HCPCS coding determinations in the first instance.

In the complaint, Cipla lists Ipsen's purported misrepresentations as follows:

- Ipsen falsely stated that, because the parties' products "are separate single source drugs, the products must have independent HCPCS codes." (D.I. 1 at ¶ 47a)
- Ipsen falsely stated that "J3490 (the code for miscellaneous drugs) must be used for Cipla's lanreotide acetate product until CMS assigns it a unique code." (*Id.* at ¶ 47b)
- Ipsen falsely stated that "[u]se of J1930 for Cipla's product may lead to payment delays, reversals, and denials." (*Id.* at ¶ 47c)
- Ipsen falsely stated that "Cipla's lanreotide acetate product is not reimbursable under HCPCS billing and payment code J1930." (*Id.* at ¶ 47d)
- Ipsen falsely accused Cipla of "falsely claim[ing] that Cipla's lanreotide acetate product was 'therapeutically equivalent' to Somatuline Depot." (*Id.* at ¶¶ 48, 61)

(*See also* D.I. 17 at 8-9) Ipsen argues that these allegations "suffer from a fatal defect: They ask this Court to decide whether InvaGen's product belongs in the same HCPCS code as Somatuline Depot." (*Id.*) But a plain reading of the alleged misrepresentations does not support this conclusion. Instead, it shows that Ipsen made multiple representations about how InvaGen's Product should be coded and reimbursed months before CMS designated an HCPCS code for InvaGen's Product. (D.I. 1 at ¶¶ 47-48, 61; D.I. 33)

At this stage of the proceedings, the court must accept the allegations of the complaint as true and draw all reasonable inferences in favor of Cipla as the non-moving party. *See Connelly*, 809 F.3d at 790-91. The complaint alleges that CMS has the exclusive authority to assign HCPCS codes. (D.I. 1 at ¶¶ 5b, 17, 47a, 59a) In contravention of CMS's exclusive authority, however, the complaint maintains that Ipsen made multiple statements about the appropriate HCPCS billing code before CMS reached a decision on the matter. (*Id.* at ¶¶ 5, 47) The

complaint does not allege that these statements were false or misleading because the codes Ipsen proposed were incorrect. Rather, Cipla maintains that the statements are "false and/or misleading because neither Ipsen nor Cipla determines the appropriate billing code for a medical treatment," and they "wrongly assume[ ] the outcome of an agency process that remains ongoing." (*Id.* at ¶¶ 5b, 5c) Ipsen's alleged misstatements regarding reimbursement problems for InvaGen's Product are likewise tethered to Ipsen's presumptions about HCPCS coding determinations that had not yet been made. (*Id.* at ¶¶ 5d, 5e) Finally, Ipsen's alleged misstatement about therapeutic equivalence does not require the court to reach an HCPCS coding determination because the complaint maintains Cipla never represented InvaGen's Product was therapeutically equivalent to Somatuline® Depot, and the court must assume the truth of this allegation. (*Id.* at ¶¶ 5a, 40, 44-45, 48, 61-62, 71-72)

Ipsen argues that its alleged misrepresentations are consistent with CMS guidance, which applies even in the absence of a CMS coding decision on a particular product.[4] (D.I. 23 at 3-4) Two sentences later, however, Ipsen describes the CMS coding guidance as "nuanced" and maintains that "[i]t is CMS's job . . . not this Court's job . . . to interpret and apply that agency guidance." (*Id.* at 4) In this regard, Ipsen's position is consistent with the allegations in the complaint—CMS has exclusive authority to apply its own guidance in making HCPCS coding

[4] In support of this assertion, Ipsen cites an "Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics," dated May 18, 2007. (D.I. 23 at 4 n.4) A document by the same name and having the same date is referenced in Cipla's complaint. (D.I. 1 at ¶ 5c) To the extent that these documents are, in fact, the same, the court may consider them as "matters incorporated by reference" into the complaint without converting the motion to dismiss to one for summary judgment. *See Kickflip, Inc. v. Facebook, Inc.*, 999 F. Supp. 2d 677, 682 (D. Del. 2013). In this case, however, there are different hyperlinks associated with the document in the complaint and in Ipsen's reply brief. (*Compare* D.I. 1 at ¶ 5c *with* D.I. 23 at 4 n.4) The hyperlink in the complaint functions, whereas the hyperlink in the reply brief does not. Ipsen does not set forth any basis for the court's consideration of the material, and the court cannot independently verify whether this material is the same as the document referenced in the complaint due to the defective hyperlink.

determinations. Nonetheless, Cipla's complaint alleges that Ipsen made affirmative representations in absolute terms about which HCPCS code "must be used" before CMS rendered a determination on the matter. (D.I. 1 at ¶¶ 5b-c, 47a-b, 58a-b, 70a-b) Far from requiring the court to make HCPCS coding determinations, the pleaded allegations boil down to a matter of chronology.

B. Cipla's Lanham Act Claim Does Not Impermissibly Intrude Upon the Federal Agencies' Regulatory Authority.

In a similar vein, Ipsen argues that Cipla's Lanham Act claim intrudes on the regulatory authority of CMS and the FDA by requiring the court to weigh in on HCPCS coding determinations and decisions on therapeutic equivalence, respectively. (D.I. 17 at 9-10; D.I. 23 at 4) A Lanham Act claim is precluded when the cause of action "would require a court to make determinations about the safety, legality, and classification of new drugs that are more properly within the exclusive purview of the FDA." *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. Dec. 13, 2016) (citing *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014)).

As explained at § III.A, *supra*, Cipla's Lanham Act claim at Count I of the complaint does not require the court to make determinations that would intrude on the regulatory authority of CMS or the FDA. *See Ciccio v. Smiledirectclub, LLC*, 2022 WL 843774, at *6-7 (M.D. Tenn. Mar. 21, 2022) (finding a false affirmative claim that the defendant's product was FDA-approved supported Lanham Act liability and was not precluded by FDA regulations). The complaint affirms CMS has the exclusive authority to make HCPCS coding determinations and explains that, in contravention of this exclusive authority, Ipsen made representations in absolute terms about which HCPCS codes should and should not apply to InvaGen's Product before CMS had rendered a decision on the matter. (D.I. 1 at ¶¶ 5, 47) The question posed by the complaint

is not whether Ipsen identified the wrong HCPCS code for InvaGen's Product. Rather, the issue is whether Ipsen misled Cipla's customers by effectively making HCPCS code determinations for InvaGen's Product while the matter was still under agency review. (*Id.*) Likewise, the complaint does not require the court to usurp the FDA's authority by making a therapeutic equivalence determination because Cipla never claimed InvaGen's Product is therapeutically equivalent to Somatuline® Depot. (*Id.* at ¶¶ 5a, 48) Instead, the complaint confirms that Cipla submitted a petition to the FDA requesting a therapeutic equivalence determination, and that petition remains pending. (*Id.* at ¶ 3)

The crux of Cipla's Lanham Act claim is the competitive harm caused by Ipsen's statements about the proper HCPCS code for InvaGen's Product and how it could impact the customers' ability to receive reimbursement. *See Par Sterile Prod., LLC v. Fresenius Kabi USA LLC*, 2015 WL 1263041, at *4 (N.D. Ill. Mar. 17, 2015) (concluding that misrepresentations regarding FDA approval status were the proper subject of a Lanham Act claim because the issue involved the deception of consumers, not whether the product was safe and effective). The complaint alleges that Ipsen made those statements before CMS reached a determination on the proper HCPCS code for InvaGen's Product pursuant to its exclusive authority. (D.I. 1 at ¶¶ 5, 47) Nothing in Cipla's Lanham Act claim requires the court to determine the proper HCPCS code for InvaGen's Product or to decide whether InvaGen's Product and Somatuline® Depot are therapeutically equivalent. Consequently, I recommend that the court deny Ipsen's motion to dismiss on preclusion grounds.

C. Cipla Sufficiently Alleges a Lanham Act Claim.

Ipsen also contends that Count I of the complaint should be dismissed because it fails to state a claim under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). (D.I. 17 at 11-15) To prevail on a claim for false advertising under the Lanham Act, a plaintiff must prove: (1) the defendant has made a false or misleading statement regarding his own product or another's; (2) that has a tendency to deceive the intended audience; (3) the deception is material and is likely to influence purchasing decisions; (4) the advertised goods traveled in interstate commerce; and (5) there is a likelihood of injury to the plaintiff. *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014) (citing *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011)). To state a claim, "the complaint must include sufficiently detailed allegations regarding the nature of the alleged falsehood to allow defendant to make a proper defense." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 632 F. Supp. 2d 362, 365 (D. Del. 2009) (internal citations and quotation marks omitted).

Ipsen argues that Count I should be dismissed because many of the challenged activities are protected under the *Noerr-Pennington* doctrine. (D.I. 17 at 12-13) According to Ipsen, government-facing activities such as lobbying CMS, filing lawsuits, and taking a public stance on regulatory questions do not constitute "commercial advertising." (*Id.*) But Cipla responds that the false statements identified in the complaint were disseminated to customers, and Ipsen cannot immunize itself from liability by repeating those statements in lawsuits or to government regulators. (D.I. 21 at 10-11)

Cipla's Lanham Act claim is not barred under the *Noerr-Pennington* doctrine, which carves out a limited immunity for actions taken to influence legislative, executive, administrative, or judicial decisions that are not undertaken with a solely anticompetitive

purpose. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135-36 (1961). Although the pleading describes complaints filed by Ipsen against the U.S. Department of Health and Human Services ("HHS"), it specifies that "Ipsen's avowed purpose in filing the [HHS] suit was to deter competition by other companies seeking to market Lanreotide Acetate products," and Ipsen used the HHS complaints to "repeat" its false or misleading claims about InvaGen's Product. (D.I. 1 at ¶¶ 53, 55) The thrust of Cipla's complaint is that "Ipsen has repeatedly made false and/or misleading statements about Cipla and [InvaGen's Product] to Cipla's customers and providers (clinics), which has undermined customers' confidence in Cipla, [InvaGen's Product], and the insurance coverage for [InvaGen's Product]." (*Id.* at ¶¶ 5, 47) The fact that Ipsen allegedly repeated those false claims in its complaints against HHS does not immunize Ipsen from liability under the Lanham Act. *See Caldron, Inc. v. Advanced Measurement & Analysis Grp., Inc.*, 515 F. Supp. 2d 565, 574 (W.D. Pa. 2007) (declining to apply *Noerr-Pennington* immunity where claims were made not only in regulatory submissions, but also to private entities within the industry).

Ipsen further contends the alleged misrepresentations about HCPCS coding status and therapeutic equivalence were not made as statements of fact and instead represented Ipsen's opinion on a contested issue of law. (D.I. 17 at 13-14) But under the Lanham Act, a statement may be actionable "if it fairly implies a factual basis," despite being "framed as an opinion." *Duty Free Ams., Inc. v. Estee Lauder Cosmetics, Inc.*, 797 F.3d 1248, 1277 (11th Cir. 2015) (internal quotation marks and brackets omitted). A Lanham Act claim need not be based on statements that are "literally false" if those statements are nonetheless misleading when viewed in full context. *Wyndham Vacation Ownership, Inc. v. Slattery, Sobel & DeCamp, LLP*, 2021 WL 4948102, at *9 (M.D. Fla. July 6, 2021).

The alleged misrepresentations identified in Cipla's complaint fairly imply a factual basis. Specifically, Ipsen's statements regarding the proper HCPCS code for InvaGen's Product suggest that CMS had already determined the proper code, an implication which can be proven true or false. (D.I. 1 at ¶ 47.a-b); *see Shure Inc. v. Clearone, Inc.*, C.A. No. 19-1343-RGA-CJB, 2020 WL 2839294, at *7 (D. Del. June 1, 2020) (explaining that statements susceptible to proof by way of objectively verifiable facts are actionable under the Lanham Act). Ipsen's representations regarding the impact of HCPCS codes on insurance coverage and reimbursement for InvaGen's Product likewise imply CMS designated an HCPCS code for InvaGen's Product and promote an unfavorable impression that InvaGen's Product will not be covered or reimbursed if a different code is used. (*Id.* at ¶ 47.c-d) Ipsen's representations regarding the proper HCPCS code for InvaGen's Product and assertions that InvaGen's Product is not reimbursable under another HCPCS code could reasonably give Cipla's customers the impression that Ipsen was describing actual facts. *See Bluegreen Vacations Unlimited, Inc. v. Timeshare Lawyers P.A.*, 2021 WL 3552175, at *9 (S.D. Fla. Aug. 11, 2021).

Ipsen also alleges that the misrepresentations cannot be considered false or misleading because they are consistent with CMS guidance. (D.I. 17 at 14; D.I. 23 at 6-7) But the complaint maintains Ipsen's statements are false or misleading because only CMS has the authority to assign HCPCS codes, HCPCS codes are not used to determine coverage for a drug, and Cipla never represented that InvaGen's Product was therapeutically equivalent to Somatuline® Depot. (D.I. 1 at ¶¶ 59, 61-62) These allegations plausibly suggest Ipsen's statements were false or misleading. At this stage of the proceedings, the court must accept Cipla's pleaded allegations as true. *See Connelly*, 809 F.3d at 790-91.

Finally, Ipsen argues that its alleged misrepresentations about therapeutic equivalence have not been pleaded with sufficient particularity[5] because the complaint does not identify "how, where, when, or to whom" the misrepresentations were made or the "medium or means" through which Ipsen allegedly disseminated the misrepresentations. (D.I. 17 at 15; D.I. 23 at 7-8) At this stage, however, the pleaded allegations are sufficiently specific. The complaint specifies that the misrepresentations were made in February 2022 to healthcare providers and wholesale distributors who were among Cipla's customers, thereby establishing when and to whom the misrepresentations were made. (D.I. 1 at ¶ 48) The complaint also offers details on the alleged genesis of Ipsen's misrepresentation, describing Cipla's press release from December 2021 which represented that "[t]he active ingredient, route of administration and strengths" of InvaGen's Product are the same as Somatuline® Depot, without making any claims as to therapeutic equivalence. (*Id.* at ¶ 5.a)

Ipsen takes particular issue with the alleged means of dissemination, citing cases that dismissed Lanham Act claims for failing to identify how the defendant spread the allegedly false information. (D.I. 23 at 8) In many of those cases, the analysis did not turn solely on a lack of specificity regarding the precise means of dissemination. *See, e.g.*, *Wakefern Food Corp. v. Marchese*, 2021 WL 3783259, at *5 n.4 (D.N.J. Aug. 26, 2021) (finding the plaintiff had not alleged what sort of statements were made, how those statements were made, or to whom they were made); *Registered Agent Sols., Inc. v. Corp. Serv. Co.*, C.A. No. 21-786-SB, 2022 WL 911253, at *3 (D. Del. Mar. 28, 2022) (finding allegation of a phone call to a single customer on

[5] Ipsen confirms it "ha[s] not invoked Rule 9(b)'s pleading standards" in arguing that Cipla's allegations of misrepresentations on therapeutic equivalence should be dismissed. (D.I. 23 at 7 n.6) Therefore, the court evaluates the sufficiency of the claim under Rule 8(a) and does not address the split of authority on whether false advertising claims under the Lanham Act should be evaluated under Rule 8(a) or the heightened pleading standard of Rule 9(b). *See Shure Inc.*, 2020 WL 2839294, at *5-6 & n.12 (citing cases).

an unspecified date was not enough to plausibly plead dissemination). Here, the complaint specifies Cipla became aware of Ipsen's misrepresentations "when a wholesaler, in response to the marketplace confusion that Ipsen created, brought the communication to Cipla's attention and informed Cipla that the communication had been distributed by Ipsen to customers." (*Id.* at ¶ 65.d) These facts do not identify the specific mode of communication and instead suggest that Cipla's wholesaler "informed" Cipla about Ipsen's communication. Nonetheless, they are sufficient to plausibly allege that Ipsen "target[ed] a class or category of purchasers or potential purchasers, not merely particular individuals." *Podiatrist Ass'n, Inc. v. La Cruz Azul De Puerto Rico, Inc.*, 332 F.3d 6, 19 (1st Cir. 2003). Under these circumstances, specific evidence of Ipsen's communications to Cipla's customers is the proper subject of discovery, and the complaint's allegations "raise a reasonable expectation that discovery will reveal evidence" of the method and scope of dissemination. *Registered Agent*, 2022 WL 911253, at *3 (internal quotation marks and citations omitted).

D. Cipla's State Law Claims Are Not Preempted.

Ipsen contends that the court should decline to exercise supplemental jurisdiction over Cipla's state law claims after dismissing the federal Lanham Act claim. (D.I. 17 at 15) Having recommended that the court deny Ipsen's motion to dismiss Cipla's Lanham Act claims, I recommend that the court deny this request as moot.

Ipsen further argues Cipla's state law claims should be dismissed because they are preempted under the doctrines of field preemption and/or conflict preemption. (D.I. 17 at 16) "Field preemption applies where 'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Farina v. Nokia Inc.*, 625 F.3d 97, 115 (3d Cir. 2010) (quoting *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471

U.S. 707, 713 (1985)). "Conflict preemption nullifies state law inasmuch as it conflicts with federal law, either where compliance with both laws is impossible or where state law erects 'an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.*

Neither field nor conflict preemption bars Cipla's state law claims in this case. Ipsen's argument for preemption is again based on its mischaracterization of the complaint and insistence that Cipla's claims require the court to substitute its judgment for CMS. (D.I. 23 at 9) For the reasons previously discussed at §§ III.A-B, *supra*, Ipsen's characterization of the complaint is not accurate, and Cipla's state law causes of action do not require the court to intrude on the exclusive authority of CMS or the FDA.

E. Cipla's State Law Claims Adequately State a Claim.

Next, Ipsen argues that the state law claims alleged in Cipla's complaint fail to adequately state a claim under Rule 12(b)(6). (D.I. 17 at 18-19) Ipsen argues for dismissal of Counts II and III of the complaint for deceptive trade practices under the Delaware Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2532 ("DTPA"), and unfair competition, respectively, because the relief requested is duplicative of the relief sought in connection with Cipla's Lanham Act claim. (D.I. 17 at 18) In *Treasury Management Services, Inc. v. Wall Street Systems Delaware, Inc.*, however, the court acknowledged the overlap among DTPA claims, claims for unfair competition, and Lanham Act claims. 16-283-SLR, 2017 WL 1821114, at *5 (D. Del. May 5, 2017). The court expressly declined to dismiss the DTPA and unfair competition claims based on the conclusion that the Lanham Act claim was sufficiently pleaded. Ipsen's cited case law is not persuasive, as it addressed post-trial findings of fact and conclusions of law and does not support a conclusion that overlapping DTPA and Lanham Act claims are barred at the

pleading stage. *See Toro Co. v. Textron, Inc.*, 499 F. Supp. 241, 248 & n.17 (D. Del. 1980). Consequently, I recommend that the court deny Ipsen's motion to dismiss Counts II and III of the complaint for alleged redundancy.

I further recommend that the court deny Ipsen's motion to dismiss Counts III and IV of the complaint for unfair competition and tortious interference, respectively. Ipsen alleges these claims should be dismissed because the complaint fails to identify any specific business relationship or opportunity that was lost as a result of Ipsen's alleged conduct. (D.I. 17 at 19; D.I. 23 at 9-10) But Delaware law does not require the plaintiff to identify customers by name when the court "can reasonably infer that specific parties were involved . . . to support a claim that 'specific prospective business relations' existed." *Military Certified Residential Specialist, LLC v. Fairway Indep. Mortg. Corp.*, 251 F. Supp. 3d 750, 758 (D. Del. 2017) (quoting *Agilent Techs., Inc. v. Kirkland*, 2009 WL 119865, at *7 (Del. Ch. Jan. 20, 2009)). Here, the complaint alleges that Ipsen's misrepresentations were disseminated among Cipla's wholesale and provider customers, and Cipla learned of Ipsen's misrepresentations from a wholesale customer who "attributed the decline in [Cipla's] sales to Ipsen's notice." (D.I. 1 at ¶¶ 48, 50, 65.d; 81) By defining the affected business relationships in terms of providers and wholesale distributors in the lanreotide acetate product market, the complaint sets forth an adequately ascertainable class at this stage of the proceedings. *Cf. Organovo Holdings, Inc. v. Dimitrov*, 162 A.3d 102, 122 (Del. Ch. 2017).

Ipsen also seeks dismissal of Cipla's trade libel claim at Count V of the complaint based on its position that the alleged misrepresentations identified in the complaint are not "false material" that was derogatory to Cipla's business. (D.I. 17 at 19) As previously discussed at § III.C, *supra*, the complaint pleads sufficient facts to support a plausible inference that the alleged

misrepresentations made by Ipsen were false. (D.I. 1 at ¶¶ 47-48, 59, 61-62) Moreover, the complaint sets forth plausible allegations about how those false statements were derogatory to Cipla's business and resulted in reduced demand for InvaGen's Product. (*Id.* at ¶ 60) I therefore recommend that the court deny Ipsen's motion to dismiss Count V of the complaint.

F. The Court Need Not Defer to the Primary Jurisdiction of CMS.

Finally, Ipsen argues the complaint should be dismissed under the doctrine of primary jurisdiction, which applies where "enforcement of the claim requires resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." (D.I. 17 at 19); *MCI Telecommc'ns Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (Fed. Cir. 1995). At the time Ipsen filed its brief in June of 2022, CMS was still actively considering the appropriate HCPCS code for InvaGen's Product, and Ipsen argued that this court's exercise of jurisdiction over Cipla's claims would not be appropriate while the matter was pending before HCPCS. (D.I. 17 at 20) In response, Cipla reiterates that consideration of the claims in this case does not require the resolution of any issues that were pending before CMS at the time of briefing. (D.I. 21 at 19)

The Third Circuit has described abstention under the primary jurisdiction doctrine as "the exception rather than the rule." *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (quoting *Riley v. Simmons*, 45 F.3d 764, 771 (3d Cir. 1995)). Consideration of four factors guides the analysis: (1) whether the issue involves technical or policy considerations within the agency's particular field of expertise; (2) whether the issue is particularly within the agency's discretion; (3) whether there is a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. *Id.* (citing *Global Naps, Inc. v. Bell Atl.-N.J.*, 287 F. Supp. 2d 532, 549 (D.N.J. 2003)). None of these factors weighs in favor of applying the

doctrine of primary jurisdiction here. As previously explained at §§ III.A-B, *supra*, the complaint in this case does not require the court to resolve technical questions regarding HCPCS coding determinations or guidance. Instead, the complaint alleges Ipsen told Cipla's customers which HCPCS code should apply to InvaGen's Product and how HCPCS coding of InvaGen's Product would impact customer reimbursements before CMS reached any conclusion on the matter. (D.I. 1 at ¶¶ 5, 47) These allegations fall within the scope of the Lanham Act and are therefore within the court's jurisdiction. Consequently, I recommend that the court deny Ipsen's motion to dismiss under the doctrine of primary jurisdiction.

IV. CONCLUSION

For the foregoing reasons, I recommend that the court DENY Ipsen's motion to dismiss. (D.I. 16)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: March 1, 2023

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE